



#36
**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

AUG - 5 1993

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fisher's Lane, Room 11-44
Rockville, MD 20857

Re: Reality Female Condom

FDA Docket No. 93E-0268

Dear Mr. Wilson:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 4,976,373 issued December 11, 1990. The application was filed on July 2, 1993, under Title II of Public Law 98 - 417, the Drug Price Competition and Patent Term Restoration Act of 1984.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination by your office on the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 USC § 156 (d)(2)(A).

C. E. Van Horn

Charles E. Van Horn
Patent Policy & Projects Administrator
Office of the Assistant Commissioner for Patents

cc: Paul Grandinetti
Levy, Zitto & Grandinetti
Suite 411
1910 K Street, N.W.
Washington, D.C. 20006-1104

Collier, Shannon, Rill & Scott

Attorneys-at-Law
3050 K Street, N.W.
Suite 400
Washington, D.C. 20007

Tel.: (202) 342-8400
Fax: (202) 338-5534

Paul Grandinetti
(202) 342-8864

747 Third Avenue
New York, New York 10017
Tel. (212) 688-4800
Fax (212) 688-6307

16-18 O'Connell Street
Level 3
Sydney, NSW 2000, Australia
Tel. 61-2-323-6788
Fax 61-2-323-2737

February 16, 1994

VIA FACSIMILE AND FIRST CLASS MAIL

FEB 22 1994

Mr. Brian J. Malkin
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
FOOD AND DRUG ADMINISTRATION
5600 Fisher's Lane, Room 15-22
Rockville, Maryland 20857

**Re: Reality Female Condom
Patent Term Extension
U.S. Patent No. 4,976,273
FDA Docket No. 93E-0268**

Dear Mr. Malkin:

Chartex International Plc provides the following information in response to your inquiry regarding the early U.K. studies of the Reality/Femidom brand female condom.

The original U.K. clinical studies occurred at the following times.

Acceptability Study -	Started	October 1987
	Finished	May 1988
Efficacy Study -	Started	February 1989
	Finished	June 1990

#32
2/22/94
Collier, Shannon, Rill & Scott

Attorneys-at-Law
3050 K Street, N.W.
Suite 400
Washington, D.C. 20007

Tel.: (202) 342-8400
Fax: (202) 338-5534

Paul Grandinetti
(202) 342-8864

February 16, 1994

747 Third Avenue
New York, New York 10017
Tel. (212) 688-4800
Fax (212) 688-6807

16-18 O'Connell Street
Level 3
Sydney, NSW 2000, Australia
Tel. 61-2-222-6788
Fax 61-2-222-8737

VIA FIRST CLASS MAIL

Mr. Brian J. Malkin
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
FOOD AND DRUG ADMINISTRATION
5600 Fisher's Lane, Room 15-22
Rockville, Maryland 20857

Re: **Reality Female Condom
Patent Term Extension
U.S. Patent No. 4,976,273
FDA Docket No. 93E-0268**

Dear Mr. Malkin:

Please note that the applicant's attorney for the application for patent term extension has the new address and telephone number as identified above.

Sincerely yours,



Paul Grandinetti

PG:jt

cc: Ms. Joan Hann


Collier, Shannon, Rill & Scott

Mr. Brian J. Malkin
February 16, 1994
Page 2

Neither an IDE nor IRB approval was required for these studies. The date on which the device was first used with human subjects as part of a clinical investigation to be filed with the FDA to secure pre-market approval of the device was in October, 1987. Therefore, the applicant identifies October 31, 1987, as the most certain date upon which such a study occurred.

If additional information is required, please do not hesitate to contact us.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Paul Grandinetti".

Paul Grandinetti

PG:jt

cc: Ms. Joan Hann